K100366

1 of 3

Section 5 – 510(k) summary Medicina enteral feeding tubes and accessories			Rev 2.0	Maxter catheters
Document reference	*Date*	*Status*	*Writer*	*510(k) number*
AQ022-3-00	26 may.-2010	Final	B Daurelle	K100366

HISTORY OF MODIFICATIONS

Date	Summary of changes	version #
28 jan.-10	Initial edition	1.0
26 may -10	Addition of a § about the risk of misconnection between the enteral feeding tube with a 6% luer taper connector used in intravascular device	2.0

Section 5
510k) Summary

JUN 14 2010

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Device :

Trade name:	MEDICINA
Common name:	Enteral feeding tubes and accessories
Regulation number:	21 CFR 876.5980
Product code:	FPD
Classification name:	Gastrointestinal tubes and accessory devices
Class:	II

Predicate devices:

510k) number:	K060944
Manufacturer:	Vygon Corporation
Trade name:	Nutrisafe 2
510k) number:	K072881
Manufacturer:	Neomed
Trade name:	Neomed Enteral Feeding tube
510k) number:	K082238
Manufacturer:	Neomed
Trade name:	Neomed Polyurethan Enteral Feeding tube

Device description: MEDICINA feeding tubes is a complete range of devices intended to the gastro-intestinal feeding of patients, with liquid nutritional media. These feeding tubes are available in several sizes (diameter and length), and two materials: PolyUrethan (PUR) and silicon (SIL). They are equipped with connecting elements that does not incorporate a Luer, and thus eliminates the risk of inadvertently connecting the system to an Intra Veinous system. The MEDICINA feeding tube features a locking connection which eliminates the risk of involuntary disconnection; voluntary disconnection is achieved by simply unscrewing the hub connections. Another benefit of the MEDICINA system is that it does not change the technique of the end-user, and therefore it does not require any special training

TABLE OF REFERENCES

DESCRIPTION	REFERENCE
Feeding tubes	MGx/yy, MGx/yyW, MGx/yyWSIL
Syringes and syringes accessories	MDxx
Accessories (sets and connectors)	CxxxM, MAxx, MCxx, MFxxx MKxx, MMxx, MNxx, , NPxx

Intended use: MEDICINA enteral feeding tubes and accessories are dedicated to the nasogastric and orogastric administration of liquid nutritional media, through the gastro intestinal tract of neonatal and pediatric patients.

Comparison with the predicates:
There are no differences between MEDICINA feeding tubes and accessories and the predicate devices; they have the same intended use and same method of use, they are made of the same material. The bench testing has demonstrated that MEDICINA feeding tubes are functionally equivalent to Nutrisafe2 and Neomed Enteral feeding tubes.

Assessment of performance and safety data:
The material of MEDICINA feeding tubes, that comes into contact with the patient, have been used for clinical purpose in enteral nutrition for a long time; they are non-irritant, non sensitizing and non cytotoxic, and found biocompatible according to ISO 10993.
Risk Assessment was conducted in compliance with ISO 14971. Verification tests performed during the design process have shown that MEDICINA feeding tubes meets performance and safety requirements, and are substantially equivalent to the predicate devices.

Risk of misconnection between the enteral feeding tube with a 6% luer taper connector used in intravascular device

The risk of misconnection is taken into account in design input of Medicina feeding tubes, with reference to EN 1615 (Enteral feeding catheters and enteral giving sets for single use and their connectors. Design and testing). The design of our connectors has been conducted to make the connection to intravenous devices mechanically impossible by greatly oversizing the dimension of Medicina tubes connectors. These connectors are bigger by approximately 1 mm compared to a standard IV 6% luer taper female connector. This has been

demonstrated in our report RAES10042009 rev 02 attachment III EN1615 section 4.2.1. (copy attached). Being compliant with EN 1615 requirements, the Medicina connection systems are considered as fulfilling the requirements 4.1 and 4.2 of ANSI ID54:1996.

Conclusion:

Based on performance evaluation and risk assessment, the MEDICINA feeding tubes and accessories can be declared as meeting safety and performance requirements, with respect of their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6
Silver Spring, MD 20993-0002

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JUN 14 2010

Re: K100366
Trade/Device Name: MEDICINA Enteral Feeding tubes and accessories
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product code: KNT
Dated: May 27, 2010
Received: June 1, 2010

Dear Mr. Daurelle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for use			Rev 2.0	Maxter catheters
Medicina enteral feeding tubes and accessories				
Document reference	*Date*	*Status*	*Writer*	*510(k) number*
AQ022-3-00	10 june.-2010	Final	B Daurelle	K100366

HISTORY OF MODIFICATIONS

Date	Summary of changes	version #
28 jan.-10	Initial edition	1.0
10 june -10	Brand name and common name clarification	2.0

510 (k) number : ~~Not known~~ (Initial submission) K100366

Device name : MEDICINA Enteral feeding tubes and accessories

Indications for use : MEDICINA enteral feeding tubes and their accessories are dedicated to the nasogastric and orogastric administration of liquid nutritional media, through the gastro intestinal tract of neonatal and pediatric patients.

Prescription Use ☑ *(21CFR part 801 Subpart D)* AND/OR ~~Over-the counter Use~~ ☐ *(21CFR part 801 Subpart C)*

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100366